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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/879,517 | 06/12/2001 | Vincent J. Sullivan | 64,149-097 | 4080 |

26253 7590 01/11/2005

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EXAMINER

EREZO, DARWIN P

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

09/879,517

Applicant(s)

SULLIVAN ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 52-65 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-51 and 66-71 is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 8, 9, 12, 13, 72, 75-77, 79, 82 and 83 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 7, 10, 11, 73, 74, 78, 80 and 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 10/04/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,644,309 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4-6, 8, 9, 12, 13, 72, 75-77, 79, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,941,867 to Kao in view of US 6,070,575 to Gonda.

(claims 1, 6, 8, 12, 13, 72, 77, 82 and 83) Kao teaches a cartridge comprising a cylindrical body **106** having opposed ends, a passage through said body through said opposed ends, a powdered medicament **107** (col. 5, line 27) stored in the passage and burstable plastic membranes **104, 112** sealing the passage at said opposite ends.

Kao is silent with regards to the membranes composed of polyolefin and wherein the membrane has a burst pressure of less than 10 ATM.

Gonda teaches a medicament cartridge having a burstable membrane, wherein the membrane has a burst pressure of less than 40 bar or 40 ATM (col. 12, lines 51-56).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the burstable membrane of Kao to have a burst pressure of less than 40 ATM (which covers the range of less than 10 ATM) since it is desirable to have a low burst pressure membrane for easier actuation of said cartridge. Furthermore, it would have been obvious to use a polyolefin membrane since polyolefin is a widely known plastic material.

(claims 4, 5, 75, 76) Kao fails to specifically teach the first and second membranes having different angles of orientation. However, the orientation of the first and second membranes is a mere design choice and that one of ordinary skill in the art could orient the first membrane at a different angle from the second membrane.

(claims 9, 79) The above combination discloses the claimed invention except for the polyethylene having a thickness of 0.3-1.5 mils and a burst pressure of less than 5 ATM. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at said limitation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Allowable Subject Matter

4. Claims 2, 3, 7, 10, 11, 73, 74, 78, 80-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 14-51 and 66-71 are allowed.

Response to Arguments

6. Applicant's arguments filed 10/04/04 have been fully considered but they are not persuasive.
7. In response to applicant's arguments, the recitation "for a manually actuated respiratory medicament delivery device" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
8. In response to Gonda failing to teach a burst pressure, it should be noted that the definition of "burst" according to Merriam Webster's Online Dictionary (www.m-w.com) is: "to break open, apart, or into pieces usually from impact or from pressure from within". With this definition, Gonda teaches a membrane having a burst pressure of 40 bar or less because at that pressure, the membrane opens to allow liquid medication to pass through.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER